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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/619,285 | 07/19/2000 | Jeno Gyuris | MIV-109.01 | 2224 |

28120 7590 04/17/2003

ROPES & GRAY
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

YU, MISOOK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 04/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/619,285

Applicant(s)

GYURIS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this c mmunicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-34 and 49-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34, and 49-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Claims 28-34, and 49-91 are pending and examined on merits.

Rejection of record is withdrawn either in view of amendment or persuasive applicant's argument.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

Claims 28-34, and 49-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/FR95/00520 (AB of IDS, Paper No. 14, publication date: 11/16/1995).

The claims are interpreted as drawn to nucleic acid encoding chimeric polypeptide comprising serum albumin with a useful heterologous peptide inserted either around amino acids 360-369, or around amino acids 450-460 of serum albumin, wherein the useful peptide has various sizes from 2 to 400 amino acids (claims 64-68, 80-91), wherein the chimeric polypeptide exhibits increased in vivo half life (claims 71-74), wherein the useful heterologous peptide is derived from various known proteins useful for treating disease or other useful purposes (claims 51-64), wherein the tertiary structure of the chimeric polypeptide is similar to native serum albumin (claim 69).

WO 95/30759 teaches nucleic acid encoding a chimeric polypeptide comprising serum albumin with a useful heterologous peptide inserted anywhere within serum albumin and a pharmaceutical composition encoding the useful chimeric peptide, wherein the useful heterologous peptide (with various peptide lengths) could be derived from various therapeutically useful protein including an angiogenesis-inhibiting proteins (see "tumoral angiogenesis" at page 4 line 9), from a protein or peptide fragments that binds to trosine kinase receptor with various in vivo functional properties. See Fig. 2-6 along with abstract, page 1-5, last three lines of page 7 to line 7 of page 9, Fig. 1-6, pages 26-30, claims 1-14, 18, 25, and 26. WO 95/30759 teaches nucleic acids

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encoding the chimeric polypeptide comprising serum albumin increases in vivo stability of various therapeutic heterologous peptide and also teaches method of making nucleic acid by linking DNA encoding various part of serum albumin to various useful heterologous proteins used as pharmacological. WO 95/30759 teaches that any therapeutically desirable peptide or polypeptide could be inserted into anywhere within serum albumin polypeptides and the resulting nucleic acid encoding chimeric polypeptide is more useful as a pharmaceutical because it is more stable and last longer in vivo: This property can reduce frequency of painful injections. 95/30759 does not specifically teaches making nucleic acids encoding the chimeric protein by inserting a therapeutically desirable peptide or polypeptide into the specific site of serum albumin recited in the instant claims. Since the entire instant specification is about increasing in vivo stability of a useful therapeutic moiety by inserting the useful therapeutic moiety into serum albumin and the specification does not teach the unexpected result by inserting a useful therapeutic moiety into the recited specific region of serum albumin, the specifically recited site is an obvious variation of the prior art in order to increase in vivo stability of a therapeutic peptide. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to insert therapeutically desirable peptide biologically active peptides or polypeptides in order to increase in vivo half life t reduce frequency of painful injections.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-34, and 49-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-33, and 54-104 of copending Application No. 09/768,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because products claimed in the instant claims are obvious variation of the product claimed in claims 28-33, 54-104 of copending Application No. 09/768,183. Note especially claims 86 and 88 of copending Application No. 09/768,183.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu

April 11, 2003



MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800—

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